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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,425	02/12/2004	Paul R. Sanberg	1372.129.PRC	4329
21901	7590	06/26/2006	EXAMINER	
SMITH HOPEN, PA 180 PINE AVENUE NORTH OLDSMAR, FL 34677			FORD, ALLISON M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/777,425

Applicant(s)

SANBERG ET AL.

Examiner

Allison M. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to a method of treating circulatory diseases, classified in class 424, subclass 93.7. *\*\*Please note claims 12-18 will only be examined upon election of "myocardial infarction" as the type of circulatory disorder, see election of species below.*
- II. Claims 19-26, drawn to a method of treating an injured tissue, classified in class 424, subclass 93.7.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related processes involving administration of umbilical cord blood; however, the related inventions are distinct because the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are not capable of use together and have a materially different design, mode of operation, function, and effect. See MPEP § 806.05(j). In the instant case, the method of Invention I is limited to treatment of circulatory disorders; the method of Invention II is not limited to the circulatory system but includes all tissues. Alternatively the method of Invention II requires identification of a site of tissue injury and treatment injured tissue; the method of Invention I does not require a step of identifying injured tissue, as the genus of 'circulatory disorders' includes non-tissue injuring diseases, such as hypertension (elevated blood pressure) or atherosclerosis (involving formation of plaques in arteries, which is not equivalent to damaged tissue). Therefore, each of the two methods have distinct limitations that not shared by the other method. A search and examination of both methods would not be co-extensive, as each method would require unique considerations.

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Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

Furthermore, upon the election of Invention I, an additional election of species is required.

Claim 1 is generic to a plurality of disclosed patentably distinct species of circulatory disorders, the species of circulatory disorders are as follows:

- a) cardiomyopathy (Claim 3)
- b) myocardial ischemia (Claims 3, 4 and 12-18)
- c) congenital heart disease (Claim 3)

The species in each group above are independent or distinct because none of the species are automatically rendered obvious by the others in its group as they are not all art recognized equivalents. Each of the different circulatory disorders listed above have unique etiologies, symptoms, complications, and treatments, and consideration of enablement for each treatment would not be mutually exclusive. Furthermore, the disclosure does not connect every species of each of the above described genres by design, structure, operation, or effect. See M.P.E.P. § 806.04(b). A requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if restriction is not required. See M.P.E.P. § 808.01(a). In this case, considering enablement, utility, and description issues for each claimed species, as well as conducting a thorough search of the prior art for each and every combination embodied by the present claims, would pose a serious burden to the examiner. Applicant is required under 35 U.S.C. 121 to elect a single disclosed

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species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

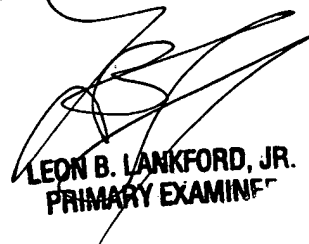
*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Allison M Ford  
Examiner  
Art Unit 1651



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER